MAY 1 8 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Apolipoprotein A1 method for ADVIA® IMS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000121

1. Intended Use
This in vitro method is intended to quantitatively measure APOA in human serum on the Bayer ADVIA IMS systems. Such measurements are used in assessing the risk of atherosclerosis.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Behring Nephelometer Analyzer	OUED	OUPG

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS APOA Reagent	06403113 (100 tests) 03395551 (250 tests)	05048948

A. Imprecision

ADVIA IMS	
Level (mg/dL)	Total CV(%)
103	1.5
156	1.7
222	2.0

BNA	
Level (mg/dL)	Total CV(%)
145	5.7

Correlation (Y=ADVIA IMS, X=BNA)

Specimen type	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
Serum	90	Y=0.95x + 5.1	5.0	0.990	34.7-204

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	APOA Conc (mg/dL)	Effect (% change)
Bilirubin (Unconjugated)	20	115	+7
Bilirubin (Conjugated)	20	128	+3
Hemoglobin	500	121	-2
Lipids (Triglycerides)	1000	149	-4

Analytical Range
Serum: 5.5 to 1,800 mg/dL

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Apolipoprotein B method for ADVIA® IMS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000721

1. Intended Use

This in vitro method is intended to quantitatively measure APOB in human serum on the Bayer ADVIA IMS systems. Such measurements are used in assessing the risk of atherosclerosis.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Behring Nephelometer Analyzer	OSAN	OUPG

3. Device / Method

Product Name	Reagent Part #	Calibrator Part #
ADVIA IMS APOB Reagent	02366787 (100 tests) 05734736 (250 tests)	04495347

A. Imprecision

ADVIA IMS	
Level (mg/dL)	Total CV(%)
121	3.4
144	3.0
203	8.3

BNA	
Level (mg/dL)	Total CV(%)
108	2.4

Correlation (Y=ADVIA IMS, X=BNA)

Specimen type	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
Serum	95	Y=1.03x – 1.7	8.9	0.966	24.2 - 173

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	APOB Conc (mg/dL)	Effect (% change)
Bilirubin (Unconjugated)	20	96	+5
Bilirubin (Conjugated)	20	107	+3
Hemoglobin	500	98	-4
Lipids (Triglycerides)*	500	102	-4

*Lipemic samples must be clarified by centrifugation prior to testing.

Analytical Range

Serum: 12 to 1,500 mg/dL

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Glucose method for ADVIA® IMS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000121

1. Intended Use

This *in vitro* diagnostic method is intended to measure Glucose in human serum, plasma and urine on the Bayer ADVIA IMS system

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Bayer Chem1® Glucose Reagent	T01-1460-53	T03-1291-62

3. Device / Method

Product Name	BAN	Calibrator Part #
ADVIA IMS® Glucose Reagent	08594722	T03-1291-62

SERUM/PLASMA/URINE

A. Imprecision

Serum

ADVIA IMS	
Level (mg/dL)	Total CV(%)
48	2.7
97	2.0
293	1.5

Chem1	
Level (mg/dL)	Total CV(%)
87	2.7
262	2.9
305	2.3

Urine

ADVIA IMS	
Level (mg/dL)	Total CV(%)
82	2.0
148	1.5
248	1.6

Chem1	
Level (mg/dL)	Total CV(%)
73	2.9
*ND	*ND
261	3.8

*Note: ND- not determined

B. Correlation (Y = ADVIA IMS, X = comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
Serum(y)	Chem1(X)	70	Y=0.97X+0.6	5.4	0.999	0-521
Plasma(y), serum(x)	ADVIA IMS	51	Y=0.99X+1.9	3.7	0.993	57-206
Urine (y)	Reference Method (CDC modified)(X)	57	Y=0.97X-1.3	5.7	0.999	3-526

C. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Glucose Conc (mg/dL)	Effect (% change)
Serum			
Bilirubin(conjugated)	25	160	0
Bilirubin(unconjugated)	25	148	+2
Hemoglobin	500	153	+2
Lipids (Triglycerides)	1000	151	+3
Urine			
Ascorbic Acid	220	155	+2
Acetaminophen	60	153	-1
Sodium Salicylate	550	152	+3

D. Analytical Range

Serum/Plasma/Urine: 0 to 700 mg/dL

Date

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 8 2000

Mr. Fredrick Clerie
Director Regulatory Affairs
Bayer Corporation
Business Group Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K000921
Trade Name: Apolipoprotein A-1 (APO-A1)
Apolipoprotein B (APO-B)
Glucose (GLU)
Regulatory Class: II
Product Code: DER, DFC, CFR
Dated: March 15, 2000
Received: March 22, 2000

Dear Mr. Clerie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000921

Device Name: **Apolipoprotein A-1 (APO-A1))**

Indications For Use:

The Bayer ADVIA IMS APO-A1 assay is an *in vitro* diagnostic device intended to measure Apolipoprotein A-1 (APO-A1) in human serum. Such measurements are used in assessing the risk of atherosclerosis.

Device Name: **Apolipoprotein B (APO-B)**

Indications For Use:

The Bayer Advia IMS APO-B assay is an *in vitro* diagnostic device intended to measure Apolipoprotein B (APO-B) in human serum. Such measurements are used in assessing the risk of atherosclerosis.

Device Name: **Glucose (GLU)**

Indications For Use:

The Bayer ADVIA IMS Glucose assay is an *in vitro* diagnostic device intended to measure glucose in human serum, plasma, or urine. Such measurements are used as an aid in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders, including diabetes mellitus and neonatal hypoglycemia.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000921

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Optional Formal 1-2-96